

CLAIMS

1. A method of treating a vulnerable plaque associated with a blood vessel of a patient, the method comprising:
 - 5 providing at least one gene therapy agent encoding at least one protein;
 - administering the gene therapy agent to a target cell population;
 - expressing the protein within the patient from a portion of the target cell population; and
 - 10 modifying the vulnerable plaque as a result of the protein expression.
2. The method of claim 1 wherein the gene therapy agent comprises a polynucleic acid selected from a group consisting of deoxyribonucleic acid and ribonucleic acid.
- 15 3. The method of claim 1 wherein the gene therapy agent comprises a vector selected from a group consisting of a plasmid, retrovirus vectors, adenovirus vectors, Herpes Simplex vectors, Semliki Forest Virus vectors, and Sindbis virus vectors.
- 20 4. The method of claim 1 wherein the gene therapy agent administration comprises at least one technique selected from a group consisting of injection, direct uptake, receptor-mediated uptake, intravenous administration, ingestion, electroporation, and precipitation.
- 25 5. The method of claim 1 wherein the gene therapy agent is administered *in vivo* the patient.
6. The method of claim 5 wherein the *in vivo* gene therapy is
- 30 administered with a balloon catheter device.
7. The method of claim 5 wherein the *in vivo* gene therapy comprises stenting the blood vessel adjacent the vulnerable plaque.

8. The method of claim 5 wherein the *in vivo* gene therapy is administered interstitially.
- 5 9. The method of claims 1 wherein the gene therapy agent is administered ex vivo the patient.
- 10 10. The method of claim 9 further comprising:
harvesting the cell population from the patient;
selecting for the portion of target cells capable of expressing the protein subsequent the administration of the gene therapy agent; and
administering the selected cells into the patient.
- 15 11. The method of claim 10 wherein the selected cells are reintroduced into a pericardial space of the patient.
12. The method of claim 1 wherein the protein is a collagen isoform.
- 20 13. The method of claim 1 wherein the protein is an A1 apolipoprotein isoform.
- 25 14. The method of claim 13 wherein the A1 apolipoprotein is a mutant Milano isoform.
15. The method of claim 1 wherein the target cell population comprises cells selected from a group consisting of muscle cells, vascular cells, hepatic cells, harvested patient cells, and donor cells.
- 30 16. The method of claim 1 wherein expressing the protein comprises secreting the protein into a bloodstream.
17. The method of claim 1 wherein expressing the protein comprises localized expression adjacent the vulnerable plaque.

18. The method of claim 1 wherein expressing the protein comprises modulating expression level with an expression cassette.
- 5 19. The method of claim 1 wherein modifying the vulnerable plaque comprises a modification selected from a group consisting of fibrous cap reinforcement, reduction of lipid pool size, modifying a lipid pool constitution, modifying an inflammation response, preventing vulnerable plaque formation, and preventing vulnerable plaque enlargement.
- 10 20. A gene therapy agent for treating a vulnerable plaque associated with a blood vessel of a patient, the gene therapy agent comprising:
at least one polynucleic acid encoding at least one protein wherein
administration of the gene therapy agent to a target cell population results in
15 expression of the protein capable of modifying the vulnerable plaque.
21. The gene therapy agent of claim 20 wherein the polynucleic acid selected from a group consisting of deoxyribonucleic acid and ribonucleic acid.
- 20 22. The gene therapy agent of claim 20 wherein the protein is a collagen isoform.
23. The gene therapy agent of claim 20 wherein the protein is an A1
25 isoform of an apolipoprotein.
24. The gene therapy agent of claim 23 wherein the A1 apolipoprotein is a mutant Milano isoform.
- 30 25. The gene therapy agent of claim 20 further comprising a vector operable attached to the polynucleic acid.

26. The gene therapy agent of claim 25 wherein the vector is selected from a group consisting of a plasmid, retrovirus vectors, adenovirus vectors, Herpes Simplex vectors, Semliki Forest Virus vectors, and Sindbis virus vectors.

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27. The gene therapy agent of claim 20 further comprising a liposome sheathing the gene therapy agent.

28. The gene therapy agent of claim 20 further comprising an expression
10 cassette encoded in the polynucleic acid.